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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/716,038	11/17/2000	Carlos Vonderwalde Freidberg	24079-1071	7272

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EXAMINER
PREBILIC, PAUL B

ART UNIT	PAPER NUMBER
3738	

DATE MAILED: 01/23/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/716,038	Applicant(s) FREIDBERG, CARLOS VONDERWALDE
	Examiner Paul B. Prebilic	Art Unit 3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *28 October 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20,29,30 and 35-44* is/are pending in the application.

4a) Of the above claim(s) *10,12-20 and 32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-9,11,29,30 and 35-44* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *5* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restrictions

Claims 10, 12-20, and 32 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in Paper No. 4.

Specification

The disclosure is objected to because of the following informalities:

The continuing data is not accurate or complete. It fails to set forth the parent application 09/156,034. It also fails to set forth the status of each parent application listed; e.g. abandoned, patented. Finally, it states that applications 09/035,114 and 09/053,200 are continuation-in-part parent application of the present application directly. However, since both of these applications were abandoned before the present application was filed, the present application could not have been straight continuation-in-part applications thereof.

Appropriate correction is required.

Information Disclosure Statement

With respect to the information disclosure statement filed January 10, 2002 (with a certificate of mailing dated October 24, 2001), certain citations were struck therefrom because they were already of record in the application by the December 18, 2001 Office action.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11

F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-9, 11, 43, and 44 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-3 and 5 of U.S. Patent No. 6,468,300 in view of Winston et al (US 6,117,166). The copending claims set forth greater detail with regard to the implant than the present claims such that the present claims nearly read thereon. However, the copending claims fail to set forth the thinned tissue as set forth in the present claims. Winston teaches that it was known to use thinned tissue in similar implants in order to improve the viability of the graft along with other reasons; see column 3, lines 23-37. Therefore, it would have been obvious to use thinned tissue in the copending claimed invention for the same reasons that Winston teaches using the same.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> **A person shall be entitled to a patent unless –**
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated by Narciso (WO 94/15583). Narciso anticipates the claim language wherein Narciso's inner layer of an artery (i.e. intima) is less than 0.45 mm in thickness; see page 8, line 9 to page 9, line 7. This is due to the fact that only one layer of the blood vessel is being used. Since the blood vessel cannot be thinned any more and because Applicant thins blood vessels to get these dimensions (see page 10, lines 1-8 of Applicant's specification), it necessarily requires that Narciso's tissue thickness is within the claimed range. For this reason, the claim language is fully met because Narciso's tissue, being the same as that claimed, is inherently capable of being used as claimed.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.**

Claims 1-3, 6-9, 11, 29, 35, 38, and 41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) alone. Winston discloses a thinned tissue on a stent where the tissue is thin enough to improve the viability of the graft and improve endothelial cell migration, but Winston fails to disclose the thickness of the tissue as claimed; see column 1, line 67 to column 2, line 4, column 2, lines 48-61, and column 3, lines 17-45, Figures 1-3, column 3, lines 16-59, and column 5, lines 4-20. However, the mere setting forth of a thickness is not considered sufficient to

support patentability and would have been obvious to an ordinary artisan in the art. In particular, MPEP 2144.04 is incorporated herein by reference and states:

> *In Gardner v. TEC Systems, Inc., 725 F.2d 1338, 220 USPQ 777 (Fed. Cir. 1984),cert. denied, 469 U.S. 830, 225 USPQ 232 (1984), the Federal Circuit held that, where the only difference between the prior art and the claims was a recitation of relative dimensions of the claimed device and a device having the claimed relative dimensions would not perform differently than the prior art device, the claimed device was not patentably distinct from the prior art device.*

With regard to claim 9, Applicant is directed to Figure 3.

With regard to claim 38, Applicant is directed to column 5, lines 16-19.

Claims 29, 30, and 36-44 are rejected under 35 U.S.C. 103(a) as being unpatentable over Love (97/24081) in view of Winston et al (US 6,117,166). Love meets the claim language fully except for the thinned state of the tissue as claimed; see pages 8 and 9. Winston et al, however, teaches that it was known to thin tissue for similar devices such that the claimed thickness is obvious as a way to improve the viability of the implant; see the abstract and the previously cited portions. Hence, it is the Examiner's position that it would have been obvious to use thinned tissue in the Love device for the same reasons that Winston et al uses the same.

With regard to claim 39, Applicant is directed to page 10, lines 6-8 of Love.

With regard to claim 36 specifically, Love teaches that it was known to have the inner and outer layers longer than the stent but not specifically by less than 5 % as claimed. However, since there is not criticality for this feature, it is the Examiner's position that it would have been prima fascia obvious to match the length of the stent

and tissue cover closely in order to reduce the cost of making the device and in order to prevent loose tissue ends from causing thrombosis of the vessel.

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Love (WO 97/24081). Winston et al disclose the use of crosslinked heterograft tissue but not bovine pericardial tissue as claimed. Love, however, teaches that it was known to make similar tissue-stent grafts out of bovine pericardial tissue, venous tissue, or many other types of tissue; Love teaches that such tissues are basically interchangeable. Hence, it is the Examiner's position that it would have been obvious to use bovine pericardial for the tissue of Winston et al because it is less expensive than most tissue and would not pose the problem of disease transmission that porcine or homograft tissue would pose.

Claim 5 is rejected under 35 U.S.C. 103(a) as being unpatentable over Winston et al (US 6,117,166) in view of Narciso (WO 94/15583). Winston et al fails to include a therapeutic material in the graft thereof. Narciso teaches that it was known to use therapeutic materials in similar implants. Hence, it is the Examiner's position that it would have been obvious to do the same for the same reasons that Narciso does the same.

Response to Arguments

Applicant's arguments filed June 3, 2002 have been fully considered but they are not persuasive.

In traversing the Winston rejections, Applicant argues that the effective filing date of the present claims is that of parent application 08/935,784 or September 23, 1997.

However, since the three independent claims contain limitations that are not supported thereby, they have a later effective filing date. In particular, claims 1 and 11 set forth a " thinned" tissue which "has a surface formed from removal of an outer layer of the tissue." Claim 29 sets forth that the outer surface of the stent is wrapped with the tissue and "configured to unwrap as the stent expands." For this reason, the Examiner believes that the effective filing date of the claims is September 17, 1998 or that of the parent application 09/156,034.

With regard to the traversal of the Narciso rejection, the Examiner has asserted that the tissue layer is inherent. He hereby asserts this fact and burdens application to show otherwise; see MPEP 2112, which is incorporated herein by reference.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any

extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Applicant should specifically point out the support for any amendments made to the disclosure, including the claims (MPEP 714.02 and 2163.06). Due to the procedure outlined in MPEP 2163.06 for interpreting claims, it is noted that other art may be applicable under 35 USC 102 of 35 USC 103(a) once the aforementioned problem is corrected.

Applicant is respectfully requested to provide a list of all copending applications that set forth similar subject matter to the present claims. A copy of such copending claims is respectfully requested in response to this Office action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Paul Prebilic whose telephone number is (703) 308-2905. The examiner can normally be reached on Monday-Thursday from 6:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott, can be reached on (703) 308-2111. The fax phone number for this Technology Center is (703) 872-9301.

Any inquiry of a general nature or relating to the status of this application should be directed to the Technology Center 3700 receptionist whose telephone number is (703) 308-0858.

Paul Prebilic
Primary Examiner
Art Unit 3738